UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF VIRGINIA
ALEXANDRIA DIVISION

GILDA HAGAN-BROWN, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14-cv-01614-AJT-JFA Hon. Anthony J. Trenga Hon. John F. Anderson
JANINE ALI, Plaintiff, v. ELI LILLY AND COMPANY, an Indiana corporation, Defendant.	Case No. 1:14-cv-01615-AJT-JFA Hon. Anthony J. Trenga Hon. John F. Anderson

PLAINTIFFS' OBJECTIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS AND COUNTER-DESIGNATIONS

Plaintiffs Gilda Hagan-Brown and Janine Ali ("Plaintiffs"), pursuant to the Court's June 24, 2015 Order, submit the following objections to Defendant Eli Lilly and Company's ("Lilly") designated deposition testimony.

I. Deposition of Dr. Madelaine Wohlreich, M.D.

Madelaine Wohlreich, M.D., is a senior research physician at Lilly, who worked on Cymbalta-related issues between 2001 and the present. Her deposition was taken on April 29, 2015 in Indianapolis, Indiana.

Pla's Objection No. 1:

Lilly has designated the following testimony:

Q. And in your experience do clinicians rely solely on the label in prescribing medicines to their patients?

MR. WISNER: Objection to form. Speculation. Lacks foundation. She can't possibly testify to what physicians do or do not rely upon, as she has not practiced in the last fifteen years.

A. I practiced for over twenty years, and I can tell you that the label is only one resource available to clinicians to learn about a drug. And it is not the resource that most clinicians use most often to learn about a drug.

Exh. 1, Wohlreich Depo. at 405:6-405:17. Plaintiffs object that Dr. Wohlreich is not qualified to render any opinion about what other doctors generally rely upon in making prescribing decisions. Such testimony is speculative, lacks foundation, and involves an incomplete hypothetical. Lilly's designation is hypocritical given Lilly has specifically moved to exclude Dr. Glenmullen's testimony about whether or not doctors rely on the label. Please note, that Plaintiffs' do not object to the immediately following question:

Q. When you were prescribing antidepressants, did you rely solely on the label?

A. Never.

Id. at 405:18-405:20.

Pla's Objection No. 2:

Lilly has designated the following testimony:

Q. Do you recall numerous questions about the U.S. package insert?

A. Yes.

Q. Okay. And this is the package insert revised as of September 2011?

A. Yes.

Q. First of all, can you look at the front page?

A. Yes.

Q. I think you mentioned that the front page contains highlights. Can you describe in your experience the purpose of the front page?

A. I believe that the FDA is aware that in the past labels were very, very detailed and had a whole lot of information that was hard to find. So when the format of the label changed around 2008, I believe it was, the new format had a summary section at the beginning. So that if a clinician didn't have time or inclination to read an entire label, he could or she could look at the highlights, which gives sort of a broad overview of what's in the label, including what's changed recently, what the drug is indicated for and approved for, the overall dosing by indication, and then importantly a summary of the safety information from a high level. There's more detail later on. But just from a very high level, under CONTRADICTIONS, WARNINGS AND PRECAUTIONS, a clinician can look at this and pretty quickly see what are the major safety issues that may be associated with this drug.

Q. And, in fact, if you looked on the left column under DOSAGE AND ADMINISTRATION on the bottom, do you see where it says, Discontinuing Cymbalta: A gradual dose reduction is recommended to avoid discontinuation symptoms?

MR. WISNER: Bottom of the page.

Q. At the very bottom on the left column.

A. Yes.

Q. And do you believe that that was appropriate information to be contained in the Highlights of Prescribing Information for Cymbalta?

A. Yes, I do.

MR. WISNER: Objection. Lacks foundation. Form.

Q. And on the right-hand column, WARNINGS AND PRECAUTIONS, do you see the about halfway down bullet that starts, Discontinuation: May result in symptoms, including dizziness, nausea, headache, paresthesia, fatigue, vomiting, irritability, insomnia, diarrhea, anxiety, and hyperhidrosis?

A. Yes.

Q. Also points to Section 5.7?

A. Yes.

Q. Do you believe that that is appropriate information to be contained in the Highlights of Prescribing Information?

A. Yes.

MR. WISNER: Objection to form. Lacks foundation. Speculation.

Q. So if you turn to Section 5.7.

A. (The witness complied.)

Q. This is the section, Discontinuation of Treatment with Cymbalta.

A. Yes.

Q. Do you recall reviewing that with Mr. Wisner?

A. Yes, I do.

Q. Prior to this deposition were you familiar with the content of this section of the label?

A. Yes.

Q. Do you believe that all the information in this section of the label is accurate?

A. Yes

Q. And you testified that the information -- I believe you testified that the information in this section is appropriate.

MR. WISNER: Objection. Lacks foundation.

Q. Is that correct?

A. Yes. I think the phrase I used was something like appropriate for its use and for the intended audience, which would be practicing clinicians in the U.S.

Q. And my quest -- last question on this label is: Do you believe that the label

contains the necessary information for clinicians to prescribe Cymbalta to their patients based on your understanding and view of what a label should contain?

MR. WISNER: Objection to form. Lacks foundation. Speculation.

A. Yes, I do.

Exh. 1, Wohlreich Depo. at 421:5 – 424:17. Plaintiffs object that Dr. Wohlreich is not qualified to render any opinion about FDA regulations, the purpose of FDA regulations, the adequacy of the Cymbalta label with regard to Cymbalta withdrawal, or accuracy the Cymbalta labeling. Dr. Wohlreich played no role in drafting the Cymbalta label and did not interface with the FDA in a regulatory capacity. Also, during questing from Plaintiffs' counsel on these topics, Dr. Wohlreich explained that she as incapable of offer such testimony:

Q. Okay. Do you have any reason to believe that Lilly could not have included those percentages on the U.S. label?

MR. STEKLOFF: Objection. Same objections and asked and answered.

A. I have no way of answering that question.

Q. Do you think those percentages should have been on the U.S. label?

MR. STEKLOFF: Objection. Same objections.

A. You know, I wasn't part of the team that drafted the label. I wasn't part of the team that submitted it and discussed it with the FDA. I don't know what discussions they had and what they -- what their considerations were, so it would be absolute speculation on my part about should they and could they have.

Q. Do you think it would have been better if those percentages were on the label for physicians trying to understand the risks of discontinuation syndrome?

MR. STEKLOFF: Same objections. Asked and answered.

A. Yeah. I can't answer that question.

. . .

Q. Doctor, do you personally believe one way or the other that these percentages should have been included with the Cymbalta label?

MR. STEKLOFF: Object to form. Asked and answered.

A. I believe that it was appropriate to include in the frequently asked questions. I do not have an opinion about whether it should have been in the label at that time or not.

Q. Do you personally believe it would have been better to have included this information in the label?

A. Think I answered that already.

Id. at 331:5-333:9. When answering questions from Plaintiffs' counsel about label content, Dr. Wohlreich was unable to "speculate," but when Lilly's counsel asked questions about label adequacy she was suddenly not speculating and full of knowledge. Simply put, this witness is not qualified to offer testimony about label adequacy, she had no role in drafting the Cymbalta label, and she openly admits that she would be speculating about label adequacy. This testimony should not be submitted to the jury.

Pla's Objection No. 3:

Lilly has designated the following testimony:

Q. With respect to Cymbalta, based on your experience working for Lilly, what is your view about the U.S. affiliate team's efforts to provide complete and accurate information to clinicians regarding Cymbalta?

MR. WISNER: Objection. Lacks foundation. Vague. Ambiguous. Speculation.

A. Providing complete and accurate medical information has always been the goal of medical team's work on Cymbalta.

Q. And does that include discontinuation-emergent adverse events?

A. Yes, absolutely.

Id. at 425:22-426:9. Plaintiffs object that Dr. Wohlreich opinion about Lilly's motive is

improper. Lilly has specifically moved to exclude Dr. Glenmullen's testimony about motive—it would be entirely improper to offer such testimony from its own current employee. Moreover, the question is vague and the testimony even vaguer. Indeed, Dr. Wohlreich cannot speculate about "Lilly's" goals and objectives as her view does not impute to all of Lilly. Finally, this is irrelevant character testimony pursuant to Fed. R. Evid. 404(a)(1).

II. Deposition of Michael Detke, M.D.

Michael Detke, M.D., was Lilly's Global Medical Director for Cymbalta and Prozac and later Executive Director of Neuroscience between July 2000 and March 2009 Lilly. His deposition was taken on April 28, 2015 in Indianapolis, Indiana.

Pla's Objection No. 4:

Lilly has designated the following testimony:

Q. Doctor, do you believe that Eli Lilly was transparent and open about the data that it collected regarding DEAEs as it pertained to Cymbalta?

MR. WOERNER: Object to form.

A. I do, and part of the reason I do is that I think that in many ways Lilly and the Cymbalta team were leaders in the field in some of the things we did regarding DEAEs. We studied them. We disclosed the data on a trial level. We published pooled data in the Perahia manuscript. We -- we did, as I stated earlier in the deposition, to my knowledge, the first-ever head -- randomized control comparison of abrupt versus taper of any of the drugs in this class. We published those data, etc.

Exh. 2, Detke Depo. at 256:19-257:8. As a threshold issue, all of Dr. Detke's testimony following "I do" is non-responsive and, thus, should not be played to the jury. More importantly, Plaintiffs object that Dr. Detke's opinion about Lilly's transparency is improper, self-serving, and speculative. Indeed, Lilly has specifically moved to exclude Dr. Glenmullen's testimony about Lilly's conduct—it would be entirely improper to offer such testimony from its former

Medical Director.

III. Deposition of Sharon Hoog, M.D

Sharon Hoog, M.D., has been employed by Lilly in various capacities including Clinical Research Physician, Research Scientist, Medical Advisor, Regulatory Advisor, and Senior Medical Advisor from 1992 to the present. Her deposition was taken on December 10, 2014 in Indianapolis, Indiana.

Pla's Objection No. 5:

Lilly has designated the following testimony:

> Q. Based on your experience as a clinician and working with colleagues in your field, prior to Cymbalta's approval in 2004, was there an understanding among clinicians who practiced in psychiatry about the potential risk of antidepressant discontinuation symptoms?
>
> MR. LECKMAN: Objection.
>
> A. Yes.

Exh. 3, Hoog Depo. at 346:4-346:11. This testimony is improper because Dr. Hoog cannot speak for what all psychiatrists knew prior to 2004 about the risks of discontinuation symptoms. Moreover, since both Plaintiffs' physicians are rheumatologists who have no expertise in psychiatry, and they both prescribed Cymbalta in 2012, Dr. Hoog's opinion about what psychiatrists knew prior to 2004 is not relevant and will only serve to confuse the jury. Lilly's designation is hypocritical given it has specifically moved to exclude Dr. Glenmullen's testimony about what doctors knew or how they interpret the label.

IV. Deposition of Matthew Kuntz

Matthew Kuntz was a former regulatory associate for Cymbalta, i.e., the primary point of contact with the FDA regarding Cymbalta, between 2007 and 2012. His deposition was taken on May 6, 2015 in Mundelein, Illinois.

Pla's Objection No. 6:

In response to Plaintiffs' designation, Kuntz Depo. at 116:1-117:23, Lilly has counter-designated the following testimony:

> Q. If a physician were to read that and think that the risks of discontinuation are about 1 percent, that would be an incorrect understanding of the US product insert?
>
> A. That would be incorrect, and I don't think that most clinicians, pharmacists and doctors would interpret it that way.

Exh. 4, Kuntz Depo. at 117 (full designation is included within transcript). Plaintiffs object to this designation because (1) Mr. Kuntz is not a medical doctor and, thus, cannot speak for what doctors think; (2) Mr. Kuntz's response to the question was non-responsive—he was asked if an interpretation was correct, but he instead testified about what most clinicians, pharmacists, and doctors think; and (3) Mr. Kuntz's testimony is speculation. Lilly's designation is also hypocritical given Lilly has sought to exclude Dr. Glenmullen's testimony concerning how doctors interpret the label.

DATED: July 15, 2015

Respectfully submitted,

/s/ Peter A. Miller
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CERTIFICATE OF SERVICE

I, Peter Miller, hereby certify that on the 15th day of July, 2015, a true copy of the foregoing PLAINTIFFS' OBJECTIONS TO DEFENDANT'S DEPOSITION DESIGNATIONS AND COUNTER-DESIGNATIONS was filed electronically with the Clerk of Court using the CM/ECF system, which will send a notification of such filing to the following:

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